IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff,** **v.** **Arthrex, Inc.** **a Delaware Corporation and** **Pearsalls Ltd.,** **a Private Limited Company** **of the United Kingdom,** **Defendants.**	)	**Civil No. 04-12457 PBS**

DePuy Mitek's Unopposed Motion Requesting Leave Of Court To File A Reply To Defendants' Response To DePuy Mitek's Motion To Preclude Defendants From Supplementing Their Expert Reports And Depositions

Pursuant to L.R. 7.1(b)(3), Plaintiff DePuy Mitek hereby moves this Court for leave to file a Reply Brief to address issues raised by Defendants Arthrex, Inc. and Pearsalls Ltd. in their Response to DePuy Mitek's Motion to Preclude Defendants from Supplementing Their Expert Reports and Depositions. Counsel for DePuy Mitek have conferred with counsel for Defendants, and Defendants do not oppose the filing of DePuy Mitek's Reply.

Dated: August 31, 2006

DEPUY MITEK, INC.,
By its attorneys,
_/s/ Erich M. Falke_____
Dianne B. Elderkin
Lynn A. Malinoski
Michael J. Bonella
Erich M. Falke
WOODCOCK WASHBURN LLP
One Liberty Place - 46th Floor
17th and Market Streets
Philadelphia, PA 19103
(215) 568-3100

Daniel J. Gleason (BBO #194900)
Michelle Chassereau Jackson (BBO #654825)
Nutter McClennen & Fish LLP
World Trade Center West
155 Seaport Boulevard
Boston, MA. 02210-2604

CERTIFICATE OF SERVICE

I certify that I am counsel for DePuy Mitek, Inc. and that a true and correct copy of:

DePuy Mitek's Unopposed Motion Requesting Leave Of Court To File A Reply To Defendants' Response To DePuy Mitek's Motion To Preclude Defendants From Supplementing Their Expert Reports And Depositions

was served on counsel for Defendants Arthrex, Inc. and Pearsalls Ltd. on this date via the Court's e-mail notification with the following recipients being listed as filing users for Defendants:

Charles W. Saber
Dickstein Shapiro
1825 Eye Street, NW
Washington, DC 2006
saberc@dicksteinshapiro.com

Raymond P. Ausrotas
Todd & Weld LLP
28 State Street, 31st Floor
Boston, MA 02109
rausrotas@toddweld.com

Dated: August 31, 2006

/s/ Erich M. Falke
Erich M. Falke

THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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Mitek's Reply In Support of its Motion To Preclude Arthrex, Inc. and Pearsalls, Ltd. From Supplementing Their Expert Reports And Depositions

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I. Overview of Reply

Under the scrutiny presented by Mitek's motion, Arthrex's initial plan to redo Dr. Gitis' expert report because errors were allegedly caused by an unspecified and unverified computer virus has now morphed into a plan to redo Dr. Gitis' expert report because some errors were allegedly caused by an unspecified and unverified computer virus, other *substantive* errors were allegedly typographical errors, and other *substantive* errors were just, well, unexplained errors. But this is high stakes litigation. The Court's scheduling order – setting expert discovery deadlines – has to be respected by the parties.

Arthrex has known from the outset of this litigation that it would be attempting to argue non-infringement on the basis of tests purporting to show that the coating on its sutures affect properties such as pliability and flexibility – the types of tests Dr. Gitis carried out – and its plan to now redo or recast large portions of his report, long after the close of expert discovery and with less than three months to trial, should not be permitted. Arthrex and Dr. Gitis should have taken more care in carrying out tests and preparing Dr. Gitis' expert report.

Upon close examination, Arthrex's stated reasons for redoing tests and changing Dr. Gitis' report at this late date are speculative (an unsubstantiated "belief" that a virus corrupted some data) or, in some instances, simply not credible (because contrary to Dr. Gitis' deposition testimony). The timing of Arthrex's notification of problems with the Gitis report and the record reflect that any problems with Dr. Gitis' report are due to inadequate preparation and lack of diligence, *not* any reasons that would justify supplementation at this late date and the substantial prejudice that such supplementation would cause Mitek.

II. Arthrex Should Not Be Permitted To "Supplement" Dr. Gitis' Report

A. Experts Are Not Permitted to Supplement Merely Because They "Deem" There to Be An Inaccuracy of Incompletion

Arthrex alleges that FED. R. CIV. P. 26(e)(1) permits an expert to "supplement" his report at his whim by merely "deeming" his report or deposition inadequate or incomplete it any respect (Arthrex Op. Br. at 2, 9-11). But, as Mitek explained in its opening memorandum, supplementation is not permitted under Rule 26 based on an expert's "inadequate or incomplete preparation." *Akeva L.L.C. v. Mizuno Corp.*, 212 F.R.D. 306, 310 (M.D. N.C. 2002); *Sharpe v. U.S.*, 230 F.R.D. 452, 462 (E.D. Va. 2005) (denying supplementation to remedy experts' "incomplete or inadequate review"). Rule 26 only permits supplementation based on "'*information that was not available* at the time'" of the report. *DAG Enterprises, Inc. v. Exxon Mobil Corp*., 226 F.R.D. 95, 109 (D. D.C. 2005) (emphasis in original) (citation omitted).

Not surprisingly, Arthrex's position -- that experts are simply permitted to supplement their reports because they could have done a better job -- has been rejected because such a standard "would essentially allow for unlimited bolstering." *Akeva L.L.C.*, 212 F.R.D. at 310. Tellingly, Arthrex's "expert deem" standard is not supported by any case citation (Arthrex Op. Br. at 2), Arthrex cites no case permitting it to supplement simply because Dr. Gitis could have done a better job[1], and Arthrex ignores all but one case cited in Mitek's opening memorandum.[2]

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[1] Arthrex's citations to three cases are no help to it here because the facts are completely different. *Wilson v. Sundstrand Corp*., Nos. 99 C 6944, 6946, 2003 WL 22012673, at *7-*8 (N.D. Ill. Aug. 25, 2003) (Arthrex Ex. 12) (permitting supplementation where opponent was on notice of proposed supplement before expert deposition began, supplementation was based on documents that expert did not have but alerted opponent he would have before deposition began, supplementation was before expert deposition was completed and before rebuttal expert reports were due, and there was no unreasonable delay); *Schumacher v. Tyson Fresh Meats, Inc*., No. CIV 02-1027, 2006 WL 47504, at *6 (D. S.D. Jan. 5. 2006) (Arthrex Ex. 10) (permitting rebuttal report to be served two weeks before expert was deposed); *Tracinda Corp. v. Daimlerchrylser AG*, 362 F. Supp. 2d 487, 506-07 (D. Del. 2005) (Arthrex Ex. 11) (addressing issue of whether expert's trial exhibits were admissible, not whether an expert was entitled to supplement).

B. Scheduling Orders Control, And An Expert Is Not Simply Permitted To Supplement Just Because It Is More Than 30 Days Before Trial

Arthrex erroneously argues that it should be permitted to supplement under Rule 26(a)(3) because it is more than thirty days before trial (Arthrex Op. Br. at 10). Where, as here, there is a Court Scheduling Order that sets forth the deadline for expert discovery, that order should control. *DAG Enterprises*, 226 F.R.D. at 110 (holding that Rule 26 is "no safe harbor" for lack of diligence and failure to show good cause to ignore the deadline for expert discovery in Court's scheduling order); *Sharpe*, 230 F.R.D. at 453-54, 462 (denying motion to supplement more than 30 days before trial because expert discovery was closed per scheduling order). Permitting Arthrex to supplement at anytime more than thirty days before trial, as Arthrex suggests, would nullify the scheduling order, result in unlimited supplementation and depositions, and permit litigants to "hold back" until thirty days before trial.

III. Arthrex Has Not Satisfied Its Burden of Showing That Dr. Gitis' Report Was Inaccurate or Incomplete In A Way That Permits Supplementation

A. Arthrex Has Not Provided *Prima Facia* Evidence of An Inaccuracy or Incompleteness Entitling It To Redo Dr. Gitis' Expert Report

Abandoning its "virus"-affected–the-entire-report-approach, Arthrex's new tactic is to seek to (i) redo friction tests based upon a mere unsubstantiated "belief" about a "virus;" (ii) make substantive changes by calling them "typographical errors;" (iii) make substantive wholesale change to Dr. Gitis' pliability test without any basis for the change; and (iv) make

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[2] Arthrex refers to only one case from Mitek's Opening Memorandum and incorrectly characterizes it as supporting Arthrex's position (Arthrex Op. Br. at 10-11). But Arthrex is wrong because the court in *Minebea Co., Ltd. v. Papst* recognized that Rule 26 "permits supplemental reports only for the *narrow purpose* of correcting inaccuracies or adding information that was *not available at the time of the initial report*," and struck the "majority" of a supplemental expert report, and permitted only some small supplementation where there was no prejudice and the expert was updating damages calculations. 231 F.R.D. 3, 7-8, 11 (D. D.C. 2005) (emphasis supplied).

other, unidentified, so-called "garden variety" corrections to the report. But in no instance has Arthrex satisfied Rule 26's requirement that it prove inaccuracy or incompleteness as a condition precedent to supplementation.

1. Dr. Gitis Should Not Be Permitted to Redo the Friction Tests on the Basis of Unsubstantiated Allegations of a Computer Virus

With respect to the alleged "virus," "computer malfunction," and "data corruption" excuses put forth by Arthrex to justify Dr. Gitis redoing his friction tests (Arthrex Op. Br. at 1, 6-7), Arthrex provides absolutely no evidence of any electronic problem that caused any inaccuracy or incompleteness in his report. After Dr. Gitis' extensive "investigation," the only evidence Arthrex can muster is Dr. Gitis' unsubstantiated "*belief*" [3] that a "*computer malfunction, possibly caused by a virus*" caused problems in the "calculations for friction" (Arthrex Ex. 3 at ¶13) (emphasis supplied).[4] No documents evidencing this virus have been produced. Dr. Gitis provides no explanation of what the errors were, how the calculations were in error, or how the computer malfunction could have caused the errors, much less the information requested by Mitek when it was first notified of the alleged virus. Thus, Arthrex fails to show that the friction calculations were inaccurate or incomplete due to this alleged virus, and it should not be permitted to supplement based on such an unsubstantiated "belief,"

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[3] Dr. Gitis' conclusion that it must have been a virus because he cannot determine another explanation is so preposterous it is barely worth addressing (Arthrex Ex. 3 at ¶16). The obvious explanation is human error in conducting the tests. Further, Mitek's experts did not, as Arthrex suggests (Arthrex Op. Br. at 5, n. 6), recognize that the data was corrupt, just that it did not make sense in light of Dr. Gitis' report (Arthrex Ex. 6 at 271:160272:7; Arthrex Ex. 7 at 27:22-28:2).

[4] Arthrex cannot even keep its story straight. Dr. Gitis carefully worded his declaration, and Arthrex carefully worded most of its opposition to say that Dr. Gitis "believed" that there was a virus (Arthrex Ex. 3 at ¶13; Arthrex Op. Br. at 1, 8, and 13). But in one instance, Arthrex states that Dr. Gitis has "determined" that certain data collected during his suture testing was corrupt (Arthrex Op. Br. at 10). That statement is unsupported.

particularly where the original belief that the virus had allegedly affected other aspects of the report is now admittedly false.

2. Dr. Gitis Should Not Be Permitted to Make Other Substantive Changes to his Report by Characterizing them as Corrections of Typographical Errors

Having abandoned its position that a virus contaminated all portions of Dr. Gitis' report, Arthrex now has other excuses for problems in the report. Now, it claims that the suture diameter reported in Dr. Gitis' report -- 0.65 mm -- was a typographical error, and that it should be 0.56 mm (Arthrex Op. Br. at 9, n.7).[5] Significantly, Dr. Gitis submits no evidence establishing that this was in fact a typographical error. Rather, he merely states that "there *appears* to be a typographical error" (Arthrex Ex. 3 at ¶34) (emphasis supplied). This unsubstantiated statement does not satisfy Rule 26's condition precedent requirement of showing an inaccuracy or incompleteness.

Further, this typo excuse is not believable. If there had been a typographical error, Dr. Gitis would have recognized it to be so at his deposition. But, even after extensive questioning about the suture diameter, he did not do so:

Q. Okay. And the diameter you say is .65 millimeters.
A. Measured this by caliper.
Q. Did you measure the diameters?
A. Yes.
Q. Of each sample?
A. Yes.
Q. Every sample?
A. Not every sample, but we measured it at least 10, 12 times, yeah.
Q. And you always got .65 millimeters?
A. Pardon me?
Q. And you always got .65 millimeters?
A. Yes.
Q. For each sample?

[5] Suture diameter affects Dr. Gitis' "pliability" results.

A. Yes.
Q. So the coated and uncoated, did you measure the diameter?
A. Yes.
Q. And they were the same?
A. Yes.
Q. No difference?
A. No difference as measured with a caliper.

Q. And you calculated an average diameter?
A. This is what we planned to do, but we didn't have to do it because many measurements that we did produced the same result, .65.

Q. Okay, if you go to -- one column says non-absorbable and synthetic absorbable sutures, and there's a number 2. Do you see that?
A. Yes.
Q. And it has diameter limits of .5000 to .599 for that. Do you see that?
A. Yes.
Q. And the diameter you used of .655 [sic 0.65]is above those diameter limits, right?
A. Yes.

(Ex. 25 at 153:11-154:9; 165:1-4; and 172:23-173:7). Further, at his deposition, it was pointed out to Dr. Gitis that his diameter measurements differed from those made by Pearsalls, the suture manufacturer (*id.* at 169:14-173:16). Yet, he never raised any issue of a typographical error at his deposition (*id.*). Most significantly, no evidence has been presented to show that it *was* a typographical error. Dr. Gitis did not record the diameter measurements when he made them, (*id*. at 174:7-10), so he has no documents that would show that this was a typographical error. Dr Gitis' inexplicable failure to keep written records of the measurements as he was making them made it more difficult for Mitek to take meaningful discovery into his test methods and results; his failure to have records should not now provide him with cover for redoing a sloppy report.

This new typo excuse, being raised for the first time *over two months* after Dr. Gitis' deposition and *four months* after Dr. Brookstein first criticized Dr. Gitis' report, is too little, too late and provides no basis for re-doing Dr. Gitis' expert report.

3. Dr. Gitis Should Not Be Permitted to Make Substantive Changes to His Report With Respect to the Pliability Testing Methods

Arthrex's counsel now asserts that Arthrex's pliability test were not performed as reported in Dr. Gitis' report *or* as Dr. Gitis testified at his deposition. Arthrex intends to redo Dr. Gitis' report to state that his pliability tests were performed at a *constant extension rate* of 0.11 mm/sec, not at a *constant loading rate* of 0.33 kg/sec, as specified in his report and as he stated at his deposition (Arthrex Op. Br. at 8, n.7).[6]

There is a difference between the two types of tests (Mitek Op. Br. Ex. 6 at ¶¶12-17), and Arthrex offers no proof (other than Dr. Gitis' self-serving statements) that Dr. Gitis actually performed a constant extension rate test, much less a constant extension rate test at 0.11 mm/sec. Dr. Gitis' typo allegations are not credible in view of his prior testimony that he determined from his own research that the test should be carried out using a *constant loading rate*, that he instructed his employees to conduct the test at a *constant loading rate,* and that he, himself, observed the tests:

> Q. Were you present for at least some of the actual testing of the pliability samples for pliability?
> A. Yes, I was present in at least some of each and every test, each type of test.
>
> Q. And how is that controlled by the machine?
> A. It is the same servo-control as we

[6] Mitek does not dispute that Dr. Gitis' data show that his pliability tests were not all run at a constant rate of loading of 0.33 kg/sec. But that does not mean that Dr. Gitis used a constant extension rate test instead of a constant loading rate test.

discussed before.
Q. It's measuring the ***force applied***?
A. Yes.
Q. And it's programmed into it to ***increase it***?
A. Yes.

Q. Who actually wrote this report?
A. I did.
Q. You did? So you put the ***0.33 kilogram per second uniform increase*** in?
A. Yes.
Q. Where did you get that from?
A. From my engineers. They gave me the number.
Q. You got that from them?
A. Yeah.
Q. Did you program yourself, did you put into the machine the ***rate at which the load should go up***?
A. No, I did not.
Q. Do you have any documents where you specified the parameters for the test that should be inputted into the machine?
A. Yes. If it's not provided in the Excel files -- what documents do you mean?
Q. Like, for example, if you wrote, either typed up or handwritten, said to your assistant, said, okay, the pliability tests, here is how I want you to run it, 50 centimeter gauge length, ***uniform increase of load at this rate***, preload of this. Did you make some kind of document?
A. No.
Q. You just orally told him?
A. Yes.
Q. Okay. And do you know how you arrived at the ***.33 kilogram per second***?
A. It was from some -- again, from the same references. From one of the references cited.
Q. Either the --
A. Rodeheaver or --
Q. Bizwada patent?
A. Yeah.

(Ex. 25 at 84:16-20; 152:1-9; and 175:1-176:11, emphasis added).

Despite this clear testimony, Arthrex now belatedly alleges that the pliability test was conducted differently than as stated in Dr. Gitis' report and at his deposition. These new allegations are just not believable on this sparse record and in light of Dr. Gitis' contradictory testimony. Thus, Arthrex has not satisfied its burden of establishing an inaccuracy that it is entitled to correct. Further, even if the test was done completely different than Dr. Gitis reported and testified, Rule 26 does not permit supplementation for such inadequate preparation. *See* cases cited in Mitek's Opening Br. at 5, n.4, 6, n.5, and 9, n.7.

4. Dr. Gitis Should Not Be Permitted to Make Unspecified, "Garden Variety" Changes to His Report

Finally, Arthrex contends it will be making so-called "garden variety" changes to Dr. Gitis' report (Arthrex Op. Br. at 9, n.7) – as if there are allowable, recognized changes to expert reports --, but Arthrex does not identify these changes. As a condition precedent to supplementing, Arthrex was required to show an inaccuracy or inconsistency that could not have been corrected at the time of the report. As Arthrex has not even identified the alleged changes, it has failed its burden of meeting Rule 26's requirements.

B. Arthrex Has Not Established that the Information About Alleged Errors Was Unavailable to Dr. Gitis Earlier

As a condition precedent to supplementing, Arthrex was required to show that the proposed supplementation is based on "*information that was not available* at the time" of the report or during expert discovery. *DAG Enters.*, 226 F.R.D. at 109-110; *Sharpe*, 230 F.R.D. at 462 (denying supplementation in part because of "unjustifiable delay"). Arthrex has not done so.

With respect to the alleged virus, Arthrex does not allege that the information that would have led to its discovery was unavailable to Dr. Gitis when he prepared his report in March 2006 or during expert discovery. Also, Dr. Gitis provides no explanation for not having reviewed his underlying data and uncovering the alleged virus in preparing his report or, at least, before his

June deposition. Dr. Gitis had plenty of time between his March report and his June deposition to find and investigate this "virus." Indeed, Dr. Gitis testified that he had checked the results in his report, which include the friction data, which he now alleges is incorrect (Arthrex Op. Br. at 6). Although Dr. Gitis alleges to have begun an investigation immediately after his deposition on June 21, 2006, he did not provide any results of this investigation until over a month after his deposition and as expert discovery was closing. Further, the results of his investigation – allegedly locating a virus that affected all his work – turned out, by his own admission, to be false.

C. Arthrex Has Basically Admitted That It Delayed Raising These Issues, Without Any Reasonable Explanation

Arthrex provides no excuse for not having raised these alleged virus-created, typographical, and other errors until, five months after Dr. Gitis' report was prepared, well after expert discovery has closed, and over two months since Dr. Gitis' deposition. Further, Arthrex has not shown why any of this information was not discovered after Dr. Brookstein's April rebuttal report, particularly when, Dr. Brookstein questioned the suture diameters used by Dr. Gitis (Mitek Op. Br. Ex. 3 at ¶49).

IV. Mitek Would Be Severely Prejudiced By Arthrex's Supplementation

Ignoring the case law, Arthrex claims that any prejudice to Mitek is irrelevant to the supplementation issue (Arthrex Op. Br. at 15). But Arthrex is wrong. Courts routinely consider the issue of prejudice because a party seeking supplementation of this nature is basically asking to reopen expert discovery and to burden its opponent. *DAG Enters.*, 226 F.R.D. at 110; *Sharpe*, 230 F.R.D. at 462 (declining motion to supplement because opponent should not be prejudiced with supplementation while it is competing discovery and prepare for trial in the confines of the Court's scheduling order).

Arthrex tries to minimize the supplementation as merely affecting a few paragraphs of Dr. Brookstein's expert report (Arthrex Op. Br. at 16-17), but that is a gross mischaracterization. If Arthrex is permitted to supplement, Mitek will want to use computer forensic experts, virus experts, and the like to analyze Dr. Gitis' equipment in order to check the veracity of the virus allegations. The veracity of these allegations are directly relevant to Dr. Gitis' credibility, as well as the substance of his opinions, and Mitek would be entitled to such discovery.

Dr. Gitis' equipment is in California, so conducting this investigation will be costly and time consuming. Further, Mitek will have to analyze each of Dr. Gitis' new test results and opinions, depose Dr. Gitis, depose Pearsalls' witnesses about the construction of the new samples being tested, have Dr. Brookstein prepare another responsive report (Mitek might ask for a different report and analyses from Dr. Brookstein because his current work was requested based on Dr. Gitis' work being so flawed), and have Dr. Brookstein deposed again. Mitek should not be burdened with the expense of these efforts. Nor should Mitek's counsel be burdened with this work while it preparing for trial, now about two months away. In fact, it is not even clear that there is sufficient time for Mitek to fully conduct its investigation and prepare expert reports in the time allotted. Arthrex and Dr. Gitis should not be rewarded for their careless work by burdening Mitek with a whole new round of issues and discovery as it prepares for trial.

V. Dr. Mukherjee Should Not Be Permitted To Supplement His Report

In its opening brief, Mitek argued that Dr. Mukherjee should not be permitted to supplement his report or deposition. Arthrex did not oppose that issue and expressed no intent to supplement his work. Accordingly, Mitek's motion with respect to Dr. Mukherjee is unopposed and should be granted.

VI. If Arthrex Is Permitted to Supplement, It Should Bear Costs to Mitek Associated with Redoing Expert Discovery

For all of the reasons outlined above and in Mitek's Opening Brief, Arthrex should not be permitted to turn back time and redo Dr. Gitis' report, as if the last six months of expert discovery never took place. If it is permitted to do so, however, Mitek should not be made to pay for Arthrex's and Dr. Gitis' sloppy work. The trial date should not slip because of Arthrex's mistakes, and Mitek should not bear additional legal costs because of Arthrex's mistakes.

Thus, if Arthrex is permitted to supplement, Mitek requests that the Court order that Arthrex produce Dr. Gitis' supplemental expert report no later than September 15, produce Dr. Gitis, Pearsalls' witnesses, and Dr. Mukherjee (who relied on Dr. Gitis' work) for deposition in Mitek's counsel's offices at an early and mutually convenient date, and compensate Mitek for the fees and costs associated with re-taking their depositions and stemming from any permitted supplementation.

VII. Conclusion

For the reasons set forth above, Mitek requests that Arthrex not be permitted to supplement Dr. Gitis' expert report. Alternatively, if Arthrex is permitted to do so, Mitek requests relief, as outlined above, to minimize the prejudicial effects to Mitek.

Date: August 31, 2006

DEPUY MITEK, INC.,
By its attorneys,

_/s/ Erich M. Falke_____
Dianne B. Elderkin
Lynn A. Malinoski
Michael J. Bonella
Erich M. Falke
WOODCOCK WASHBURN LLP
One Liberty Place - 46th Floor
17th and Market Streets
Philadelphia, PA 19103
(215) 568-3100

Daniel J. Gleason (BBO #194900)
Michelle Chassereau Jackson (BBO 654825)
NUTTER MCCLENNEN & FISH LLP
World Trade Center West
155 Seaport Boulevard
Boston, MA. 02210-2604
(617) 439-2000

CERTIFICATE OF SERVICE

I certify that I am counsel for DePuy Mitek, Inc. and that a true and correct copy of:

Mitek's Reply In Support of its Motion To Preclude Arthrex, Inc. and Pearsalls, Ltd. From Supplementing Their Expert Reports And Depositions

was served on counsel for Defendants Arthrex, Inc. and Pearsalls Ltd. on this date via the Court's e-mail notification with the following recipients being listed as filing users for Defendants:

Charles W. Saber
Dickstein Shapiro
1825 Eye Street, NW
Washington, DC 2006
saberc@dicksteinshapiro.com

Raymond P. Ausrotas
Todd & Weld LLP
28 State Street, 31st Floor
Boston, MA 02109
rausrotas@toddweld.com

Dated: August 31, 2006

/s/ Erich M. Falke
Erich M. Falke

IN THE UNITED STATES DISTRICT COURT FOR THE

DISTRICT OF MASSACHUSETTS

DEPUY MITEK INC., a Massachusetts Corporation, Plaintiff, vs. ARTHREX, INC., a Delaware Corporation, and PEARSALLS LIMITED, a Private Limited Company of the United Kingdom, Defendants.	:	Civil Action No. 04-12457

Washington, D.C.

Wednesday, June 21, 2006

Videotape Deposition of:

DR. NORM GITIS,

The witness, was called for examination by counsel for the Plaintiff, pursuant to notice, commencing at 8:15 a.m., at the law offices of Dickstein Shapiro Morin & Oshinsky LLP, 2101 L Street, Northwest, Washington, D.C., before Dawn A. Jaques, Certified Shorthand Reporter and Notary Public in and for the District of Columbia, when were present on behalf of the respective parties:

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Q. Thank you. The testing that you did in connection with this case in your reports, who actually did the testing?
A. I did it together with two engineers in my lab.
Q. Okay. And what engineers?
A. Michael Vinogradov and Vishal Khosla.
Q. Can you spell their names, please?
A. Michael V-I-N-O-G-R-A-D-O-V, Vinogradov, and Vishal K-H-O-S-L-A, Khosla. One is from Russia, one is from India.
Q. I'm going to guess Mr. Vinogradov is from Russia?
A. Good guess.
Q. What did Mr. Vinogradov do with respect to the test? What was his role?
A. He helped to set up the testers and modules, and he did some of the tests together with me.
Q. What tests did Mr. Vinogradov do?
A. Most of the tests, or maybe all of the tests we kind of did together.
Q. So Mr. Vinogradov was involved in all the tests?
A. Yeah, and same thing with Mr. Khosla.

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Q. How did their roles, Mr. Vinogradov and Mr. Khosla's roles, differ?
A. Vinogradov is a more senior member of the team, and he was involved fully in all the tests that we did for Ethicon and U.S. Surgical, and he was the only one who remembered something from those old tests.
So Michael was more senior. He was helping mostly in setting up the tests, and Vishal was helping mostly in running the tests, and I was like in and out. I was not there hundred percent of the time.
Q. Okay. You weren't there 100 percent of the time for the set-ups; is that right?
A. For all of it, for the set-ups and the test. So they will do the set-up, I would come approve or not approve, and then we would start running tests. I would come out, come back and see what is happening.
Q. Did you approve each set-up after it was done before the test was run?
A. Yeah, of course.
Q. You visually looked at each set-up?
A. Yes.
Q. And in terms of when the tests were

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running, most of these tests took less than a minute, right, actual running time?
A. Not really. Depends on what you call the running. You have to set up the specimen, and for some of them you have to make notes, so most of them took several minutes. So, yeah, I was in and out of the room during this test.
Q. And what percentage of the test did you actually see?
A. Maybe between 25 and 50 percent.
Q. Okay. Is there any of the tests that you didn't actually witness the test being done of the tests that were done? Let me ask a better question.
There's pliability tests that you've described. Were you present for at least some of the actual testing of the pliability samples for pliability?
A. Yes, I was present in at least some of each and every test, each type of test.
Q. Okay. So you weren't present the whole time for this set-up and loading of each sample; is that right?
A. That's correct.
Q. And from the tests that were done, data

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was generated, correct?
A. Yes.
Q. Okay. And all the data that was generated, was that computer generated?
A. Yes.
Q. And then from the computer-generated data, some calculations and results were presented?
A. Yes.
Q. Who did the calculations?
A. Two of them, Michael and Vishal.
Q. Okay. What was your involvement in the calculations?
A. We discussed the formula used, and I checked the results.
Q. Did you check every result, or just kind of spot check it?
A. I checked most of the results.
Q. Okay. Did you instruct Mr. Vinogradov and Mr. Khosla as to how to -- as to what formulas to use and how to generate the results from the data?
A. How to generate results, I don't have to instruct them. They know how to do it.
What formula to use, maybe it was not my

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right?
A. Yes.
Q. And then the second, is Z a zero?
A. Yes.
Q. Does that tell you this is where the test started after the preload was applied?
A. I'm sorry, I have to think much more how to read this raw data.
Q. Have you read the raw data before today that was used for the test?
A. In my life? For this testing? No.
Q. No, okay.
A. I was looking only at the results.
Q. Okay. Do you see the force column?
A. Yes.
Q. And at the time, .504 -- the force being applied to the specimen is .55 kilograms, right?
A. Yes.
Q. In your paper, in your page 3 --
A. Yes.
Q. -- of your report, you say the suture was preloaded with a tension of .5 kilograms. Preloaded suture was then pulled at a force, uniformly increasing at a rate of .33 kilograms per second.

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A. Yes.
Q. Now, the uniform increase in rate you're talking about, is that uniform increase in the load that's applied to the specimen?
A. Yes.
Q. So you applied a .5 kilogram preload to specimen, right?
A. Yes.
Q. And then you increase that .5 kilogram preload at a rate of .33 kilograms per second uniformly, right?
A. Yes.
Q. Okay. So at time --
A. Uniform in time, yeah.
Q. So at, say when the actual -- after the preload is applied, if you call that time zero, after the first second, the load applied should be .5 --
A. Plus .33.
Q. Would be .83?
A. Yes.
Q. And then it goes up?
A. Yes, that's correct.
Q. And it goes up uniformly, so for each --
A. Yes.

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Q. And how is that controlled by the machine?
A. It is the same servo-control as we discussed before.
Q. It's measuring the force applied?
A. Yes.
Q. And it's programmed into it to increase it?
A. Yes.
Q. Okay. So the column F sub Z, after the preload was applied, should that be going up at a rate of .33 kilograms per second?
A. Yes.
Q. What we're going to do is we have a CD with the data on it, if that's easier for you to look at.
A. Yeah, it will be much easier.
Q. It's Bates number ARM 25902. It's entitled CETR Raw Data.
Do you have a later flight option?
A. I thought we already finished.
Q. Not quite.
A. Go on with the rest of your questions.
Q. Let me ask you while he's loading that up, I'll ask you a question. Page 3 at the top

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you say the suture of 50 millimeters in length.
A. Yes.
Q. So you used a 50 millimeter gauge line for each sample?
A. Yes.
Q. Okay. What device did you use to measure the gauge lines?
A. Caliper.
Q. Caliper?
A. Yeah.
Q. Okay. And the diameter you say is .65 millimeters.
A. Measured this by caliper.
Q. Did you measure the diameters?
A. Yes.
Q. Of each sample?
A. Yes.
Q. Every sample?
A. Not every sample, but we measured it at least 10, 12 times, yeah.
Q. And you always got .65 millimeters?
A. Pardon me?
Q. And you always got .65 millimeters?
A. Yes.
Q. For each sample?

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A. Yes.
Q. So the coated and uncoated, did you measure the diameter?
A. Yes.
Q. And they were the same?
A. Yes.
Q. No difference?
A. No difference as measured with a caliper.
Q. Okay. I'm going to show you -- here's the computer. I think that your data is in files, and there's one that says "Modulus Raw Plots." Do you see that? I believe that's your --
A. Yeah.
Q. If you could open up that file of the modulus raw plots file. I think that's what we're looking at here. Is this coated or uncoated, or is it both?
A. No, it seems to be opening. Hopefully it will open.
Q. That's the uncoated graph, right?
A. Maybe I will reduce magnification. Yeah.
Q. Can you find -- we were looking at the printouts of the coated. Can you find the coated

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in that file?
Okay, there's the graph for the coated, right? Okay. Now, if you go to the data for the coated that we were looking at on the printouts, there's the data, right?
A. Yes.
Q. Okay. And we're looking at here part way down. If you go all the way to the top, right there, that is the top, this is the setting of the preload, right?
A. Yes.
Q. Okay. Now, could you go down and find where the preload stops and the test, if you will, if you want to call it that, the test part of it begins?
A. Okay, one sec. I was there, and I just lost it. Erich, we need you, only your hands can work with this. I just saw it a second ago.
Q. So that's where the actual --
A. You'll see 10 seconds. 10 seconds were over, and preload was over. I'm looking at time.
Q. Right. And -- okay. I see on the printout, see, for example, on column 2 it says No. 2, radius, velocity, duration?
A. Because you know what, because I will

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explain for a second -- I'm sorry, did you ask me a question, why it's every time 10.04 or 10.05 or 10.06?
Q. No.
A. Because of its servo-control, so it always measures the real time. It says go for 10 seconds, but it measures with the accuracy of hundredths of a second, so every time it's 10.06, 10.05, 10.04. Every time it's slightly different.
Q. I'm just going to move it over.
A. Yeah, sure, sure.
Q. What's going on here?
A. I don't know what Erich did to it.
Q. Now we're all the way on the left-hand side. See it says radius minus 13.136, 10.05. Looks like that's in the third column, right?
A. Yeah, perfect. This is what we see now, right?
Q. I don't know that we're seeing all the digits in the spreadsheet. Is there more digits in there?
A. Maybe if we increase the width of the column. Yeah, now we see.
Q. So, for example, if this is Sample 2, the test is actually starting at line 4694.

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A. Right.
Q. Right, which would be this line here for Sample 2, see how it matches up 0.5, 13.629, 30.3790. See that?
A. Yeah.
(DePuy Mitek Exhibit No. 396 was marked for identification.)
BY MR. BONELLA:
Q. Okay. I'm going to mark 396 as this page where it looks like the preload had finished and the testing is starting for at least Samples 1, 2 and 3. Do you see that?
A. Yes.
Q. Okay. So let's just look at Sample 2. Sample 2 at time zero, right --
A. Yes.
Q. -- the load is .5?
A. Yes.
Q. And time zero is measured in seconds, right?
A. Yes.
Q. And you said the load is going up .33 uniformly per second?
A. Yes.
Q. So at time T equals 1, the load should

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A. Yes.
Q. Is there an assumption in the test that it's a uniform increase in --
A. Yes.
Q. And that assumption is wrong?
A. No, I didn't say so.
Q. I didn't say you did. I said if the assumption is wrong, how does that -- what does that do to the results?
A. It would have no result -- no effect on the results.
Q. Even if it wasn't uniform?
A. Yes.
Q. Why is that?
A. Because we loaded sutures uniformly or not, whether we loaded with -- at the rate of .3 kilogram per second or .03 kilogram per second, we saw clear differences between coated and uncoated, clear repeatable statistically different results for coated and uncoated sutures.
Q. If you didn't load them uniformly, right, each one was loaded at a different rate --
A. Yes.
Q. -- you would generate different strains per time, right?

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A. Yes.
Q. So the graphs that generated would not be correct?
A. No, the graphs would still stay because this graph is just one column versus another column. You have column -- we just looked with you at the computer. You have column force, and you have column strain, and you just plot force versus strain or strain versus force, and whether it was increasing uniformly or not, it cannot change this graph.
Q. Let me ask you a different question. If the loads didn't increase at a uniform rate, at the same uniform rate on each sample, you can't really compare the graphs to each other?
A. If for every sample the rates were different, it would jeopardize the results.
Q. Okay. You assumed in this test that the diameter was constant along the length of each specimen, right?
A. I didn't understand your question.
Q. Each specimen, for the pliability test, you assumed that the diameter --
A. We recall specimens at 50 millimeter from the suture.

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Q. Yeah. You assumed that the diameter was constant along those lengths?
A. No, we didn't make this assumption.
Q. You didn't?
A. No.
Q. Well, you used -- did you use 0.65 millimeters in calculating all the stiffness data that's presented in Table 2?
A. Yes.
Q. So did you actually measure along every point of the length of every suture?
A. No.
Q. Okay. So you did some measurements?
A. We assumed that this data is the average diameter, but we did not assume -- we did not make any assumptions on each cylinder being ideally -- ideally cylindrical because nothing is ideal in this life.
If you want to characterize cross section of the cylinder, you have to deal with average parameters for the cylinder.
Q. Well, doesn't the test assume that applying a -- you measured diameters along the length of some specimens for the pliability tests?
A. Yes.

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Q. And you calculated an average diameter?
A. This is what we planned to do, but we didn't have to do it because many measurements that we did produced the same result, .65.
Q. Who measured the diameter?
A. Michael Vinogradov.
Q. How much experience does he have in measuring suture diameters?
A. In measuring suture diameters, his experience is very, very limited, but in measuring diameters of cylinders, he has plenty of experience.
Q. How about in measuring diameter of specimens on the order of the size of a suture?
A. We have lots of experience for this.
Q. No, him personally.
A. Him personally.
Q. Does the device that you used to measure diameter, specifically what was the device used?
A. Caliper.
Q. What's the type and name of the caliper?
A. Made by a Japanese company called Mitutoyo, but I don't remember the particular model.
Q. Was it ditigal or --

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A. Yeah, digital, sure.
Q. Okay. How many decimal places does it read out in?
A. I do not remember.
Q. Okay. Do you know what its accuracy or sensitivity is?
A. I do not remember.
Q. Do you know if it's designed to measure specimens on the order of sutures? I'm sorry, do you know if the caliper that was used is specifically designed to measure suture diameters?
A. I know that it was not designed specifically for sutures. It's just a general engineering caliper that we use in our lab. We have several of them. We ordered them together, they are from the same bunch, Mitutoyo calipers, but I don't believe that Mitutoyo targets suture market with those calipers.
Q. Okay. Doesn't the test -- the tests that you're doing -- well, are you saying that you -- did you verify that the specimens that were tested in the pliability tests were actually circular in diameter?
MR. TAMBURO: Objection, vague.
THE WITNESS: No, we did not.

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BY MR. BONELLA:
Q. Okay. So there was an assumption that thy were circular in diameter?
A. They looked circular.
Q. Okay, but they're very small?
A. Yes.
Q. Okay. And it was also assumed that they're circular in diameter along the entire length of the specimen, the 50 millimeters that was tested in pliability tests?
A. We did not need this assumption. If you are talking about our calculations of the moment of inertia where we used diameter of the cylinder, yes, it was assumed that average diameter was .65, but we did not need to go and to measure each and every cross section over the length of 50 millimeters, because in practical engineering, you just need to have the average diameter for your calculations of the moment of inertia.
Q. Okay. How many measurements did you take of diameter?
A. I believe I already answered. We did minimum 10, 12 on the coated, and minimum 10, 12 on the uncoated.
One of the -- why we did it separately

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on coated and uncoated, because in the beginning we were not sure whether coating would introduce some thickness, so we did it very carefully.
MR. TAMBURO: Do you want to break for lunch soon?
MR. BONELLA: Yeah. Let's just finish this up.
THE WITNESS: It's about end. Let's finish.
(DePuy Mitek Exhibit Nos. 399 and 400 were marked for identification.)
BY MR. BONELLA:
Q. I'm going to show you DePuy Mitek Exhibit 399 and DePuy Mitek Exhibit 400. I ask you if you've ever seen these documents before?
A. I don't remember ever seeing these documents.
Q. Okay. Do you see where -- they're from Pearsalls?
A. Yes.
Q. And they're dated February 17th, 2006. Do you see that?
A. Where shall we see the date?
Q. Down the bottom on the left-hand side.
A. Oh, yes.

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Q. And do you see on Exhibit 399, do you see it says -- underneath here it says coated with Nusil Med2174 Silicone?
A. Yes.
Q. And if you look at Exhibit 400, in the product line, third line of the document, it says Blue Fibre Wire Uncoated. Do you see that?
A. Yes.
Q. You don't know if these documents pertain to the samples that you tested, do you?
A. I don't know.
Q. They weren't provided to you?
A. They have not been provided.
Q. If you look at Exhibit 399 and look under the diameter column or row, there's an average/mid/max?
A. Yes.
Q. And the average diameter was .586, minimum was .570, and the max was .599. Do you see that?
A. Yes.
Q. This is for a coated sample. It's different than what you assumed -- or you used, I'm sorry, .65?
A. Yes.

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Q. Okay. Can you explain why there would be a difference if this applies to the same suture?
MR. TAMBURO: Objection, calls for speculation.
THE WITNESS: I cannot explain. I don't know --
BY MR. BONELLA:
Q. And you agree that the .65 that you used is above the maximum that was measured at least for this sample in Exhibit 399?
A. Yes.
Q. If you look at Exhibit 400, for the uncoated the diameter average was .600 millimeters, the min was .570, and the max was .635. Do you see that?
A. Yes, I do.
Q. And so for this uncoated sample in Exhibit 400, the maximum diameter that was measured is less than the diameter that you used, right?
A. Yes.
Q. Can you explain that?
A. No, I cannot.
Q. And do you see how the uncoated in

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Exhibit 400 and the coated in 399 had different measurements for average/minimum/maximum diameters?
A. Yes -- no. I see the same minimums, but different averages and maximums.
Q. Yes, I'm sorry, thank you. But didn't find any difference in the diameters when you measured them?
MR. TAMBURO: Objection, mischaracterizes testimony.
BY MR. BONELLA:
Q. I'm sorry, did you find differences in diameters between the coated and uncoated samples that you tested in the pliability tests?
A. We specifically looked for it, and we didn't find the differences.
Q. Okay. Now, are you familiar with the USP sizing for diameters?
A. No, I am not.
Q. Okay. Are you familiar with a No. 2 designation for suture?
A. No.
Q. Did you ever hear of a diameter range for a No. 2 suture?
A. No. Maybe I heard about it either from

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the deposition of Dr. Mukherjee or from some rebuttal or report of Dr. -- of your expert witness.
Q. I'll show you the next exhibit.
THE VIDEOGRAPHER: I need to change. It takes 20 seconds.
MR. BONELLA: That's all right, keep going.
(DePuy Mitek Exhibit No. 401 was marked for identification.)
BY MR. BONELLA:
Q. DePuy Mitek Exhibit 401 -- I'm sorry, I labeled the inside page, but it's a 4-page document. Part of it is not from the same document, but the last page is suture size and diameter chart. Do you see that?
A. Yes, I do.
MR. TAMBURO: I'm sorry, are you representing this as a USP chart?
MR. BONELLA: The last page is.
MR. TAMBURO: The last page is.
BY MR. BONELLA:
Q. Okay, if you go to -- one column says non-absorbable and synthetic absorbable sutures, and there's a number 2. Do you see that?

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A. Yes.
Q. And it has diameter limits of .5000 to .599 for that. Do you see that?
A. Yes.
Q. And the diameter you used of .655 is above those diameter limits, right?
A. Yes.
Q. Did you test any sutures other than No. 2 size suture?
A. I did not test any sutures rather than those spools I received from the law firm.
Q. If the diameter of the coated and uncoated were different, that would change the pliability test data stiffness that's presented in table -- on page 4 of your report, correct?
A. That's correct.
Q. Okay, you want to break for lunch?
MR. TAMBURO: Sure.
THE VIDEOGRAPHER: This is the end of Tape 2, beginning of Tape 3. Off the record at 12:45:46.
(Lunch break taken.)
THE VIDEOGRAPHER: This is the beginning of Tape 3 in the deposition of Dr. Norm V. Gitis. On the record -- excuse me, can we go off the

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record? Off the record at 1:43:13.
(Pause in the proceedings.)
THE VIDEOGRAPHER: This is Tape 3 in the deposition of Dr. Norm V. Gitis. On the record at 1:44:58.
BY MR. BONELLA:
Q. Were there any recordation of the diameter measurements that you said were made? Is there anywhere that was recorded?
A. No, it was not.
Q. According to the data, it shows for the pliability tests that you had eight samples of coated and uncoated that were reported in tests?
A. Yes.
Q. Okay. Other than the eight, did you do any other samples that aren't recorded there?
A. No.
Q. Why did you choose eight?
A. Because among the references we cited, some people tested five, some seven, some ten, so we saw eight as somewhere in the middle.
Q. Okay. Any other reason?
A. Huh?
Q. Any other reason?
A. That's about it.

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Q. Who actually wrote this report?
A. I did.
Q. You did? So you put the 0.33 kilogram per second uniform increase in?
A. Yes.
Q. Where did you get that from?
A. From my engineers. They gave me the number.
Q. You got that from them?
A. Yeah.
Q. Did you program yourself, did you put into the machine the rate at which the load should go up?
A. No, I did not.
Q. Do you have any documents where you specified the parameters for the test that should be inputted into the machine?
A. Yes. If it's not provided in the Excel files -- what documents do you mean?
Q. Like, for example, if you wrote, either typed up or handwritten, said to your assistant, said, okay, the pliability tests, here is how I want you to run it, 50 centimeter gauge length, uniform increase of load at this rate, preload of this. Did you make some kind of document?

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A. No.
Q. You just orally told him?
A. Yes.
Q. Okay. And do you know how you arrived at the .33 kilogram per second?
A. It was from some -- again, from the same references. From one of the references cited.
Q. Either the --
A. Rodeheaver or --
Q. Bizwada patent?
A. Yeah.
Q. So this pliability test is actually -- the test you did is actually a tension test, isn't it?
A. It's a pliability test.
Q. It's also a tension test, right?
A. Yes.
Q. And in order for it to be a pliability test, certain assumptions have to be true, right?
A. Yes.
Q. Is one of the assumptions that the compressive and tensile modulus of the specimen -- let me rephrase that.
Is one of the assumptions that the compressive and tensile moduli are the same for

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the specimen?
A. It was not specifically the assumption for this test.
Q. You didn't assume that one way or the other?
A. No, we did not.
Q. You didn't consider it?
A. Again, as we discussed before lunch, we just decided to use the same test as our customers.
Q. So you didn't use -- you didn't consider whether that was an assumption that goes into applying this test for stiffness then?
MR. TAMBURO: Objection, vague.
THE WITNESS: No, we did not spend much time on considering assumptions of our customers.
BY MR. BONELLA:
Q If the compressive and tensile moduli for the FiberWire specimens you tested are not the same, how would it affect the pliability test results that you've prepared?
A It's hard to say. Depends on their levels.
Q If they're different, if the compressive and tensile moduli for the FiberWire samples are